

Training and Preparation for Administering COVID-19 Vaccinations under the Auspices of the Virginia Department of Health

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I. Purpose

The purpose of this document is to provide uniform guidance and training for all staff providing COVID-19 vaccinations. Public health professionals are the gold standard for vaccination campaigns. To maintain the trust and confidence of the public, this vaccination campaign must be undertaken with the utmost attention to detail in vaccine storage and handling, vaccine administration, correct timing of vaccination with the second dose, and thorough follow up on any potential adverse reactions.

II. Individuals Authorized to Vaccinate

Table 1 below provides a summary of roles that are authorized to perform different actions related to vaccine administration (vaccinating, mixing etc.) along with supervision requirements. Please also review Sections III & IV of this document for further information on authorization of various roles. **Remember, all roles that are authorized to vaccinate MUST complete the Skills Assessment Checklist for the vaccine they will administer** (included as Appendices in this document).

Table 1: Vaccinator Roles

Provider Credentials*	Authorized to Vaccinate	Supervision Needed to Vaccinate	Authorized to mix/reconstitute/dilute	Supervision Needed to mix/reconstitute/dilute
MD, DO**	Yes	None needed	Yes	None needed
PA**	Yes	None needed	Yes	None needed, once trained
RN**	Yes	None needed	Yes	None needed, once trained
Nurse Practitioner (not in independent practice)**	Yes (functions under RN license)	None needed	Yes	None needed, once trained (functions as an RN)
LPN**	Yes	Yes. Supervision needed by RN (can also be provided by MD, DO)	No	N/A
Pharmacist**	Yes	No	Yes	None needed, once trained

Pharmacy Intern	Yes	Yes. Supervision can be provided by pharmacist ONLY	Yes	Yes. Supervision and second check can be provided ONLY by pharmacist
Pharmacy Technician	Yes	Yes. Supervision can be provided by pharmacist ONLY	Yes	Yes. Supervision and second check can be provided ONLY by pharmacist
Other Health Professionals ***	Yes	Yes	N/A	N/A
EMS Providers**	Yes	No	No	N/A
Nursing Students****	Yes (only as per §18VAC90-27-110) School must certify students have been properly trained in vaccination administration.	On-site oversight from health care providers whose scope of practice includes vaccine administration is also required.	No	N/A
Other VA Students of Health Professions listed above (in good academic standing)****	Yes. School must certify that students have been properly trained in vaccination administration.	On-site oversight from health care providers whose scope of practice includes vaccine administration is also required.	No	N/A

* Providers must have a license from Virginia, or another US State as per the [PREP Act](#) (only physicians, registered nurses, and licensed practical nurses), with the exception of Active Duty Military and Military Medical Personnel. Virginia MDs, DOs, and DPMs can search for their licenses [here](#). If a provider is licensed in a state other than Virginia, they will be required to provide VDH with their license documentation.

Active Duty Military do not require a state-specific license as per [§ 54.1-2901](#) (DHP regulations may not prevent the performance of the duties of any active duty health care provider in active service in the Army, Navy, Coast Guard, Marine Corps, Air Force, or public health service of the United States at any public or private health care facility while such individual is so commissioned or serving and in accordance with [their] official military duties) and [§ 54.1-106](#) (Any commissioned or contract medical officers or dentists serving on active duty in the United States armed services and assigned to duty as practicing commissioned or contract medical officers or dentists at any military hospital or medical facility owned and operated by the United States government shall be deemed to be licensed pursuant to this title).

Medical Military Personnel (an individual who has recently served as a medic in the United States Army, medical technician in the United States Air Force, or corpsman in the United States Navy or the United States Coast Guard and who was discharged or released from such service under conditions other than dishonorable **as per § 2.2-2001.4. Military medical personnel; do not require a state-specific license.** More specifically, military medical personnel may practice and perform certain delegated acts that constitute the practice of medicine or nursing, reflecting the level of training and experience of the military medical personnel and under the supervision of a licensed physician or podiatrist.

****** For example, under the [PREP Act](#) MDs, DOs, RNs, LPNs, pharmacists, pharmacy interns, and pharmacy technicians with an expired **out of state** license due to retirement in the past five years that is in good standing can also prescribe (MD, DO) or administer (RN, LPN, pharmacist, pharmacy intern, pharmacy technician) vaccines in Virginia. Please note that in all cases, retired individuals cannot put any former credentials on their name tag during the vaccine clinic. Only those with active licenses can use credentials like MD, RN, etc.

******* The other health professionals category includes dentists, optometrists, respiratory therapists, midwives, podiatrists, and veterinarians as indicated in the PREP Act.

******** Check Section III, numbers 4 & 5 for more guidance about students of health professions, which includes students of medicine, nursing, dental medicine, midwifery, optometry, paramedic, pharmacy, physician assistant studies, podiatry, respiratory therapy, veterinary medicine, and emergency medical technician students (advanced or intermediate EMTs).

Individuals Authorized to Vaccinate When a Prescriber is Not on Site:

Under [§54.1-3408](#), the following individuals may vaccinate adults when a prescriber is not on site:

- 1. Pharmacists**
- 2. Registered Nurses (RNs)**
- 3. Licensed Practical Nurses (LPNs; only under the supervision of an RN)**
- 4. Retired MDs, pharmacists, RNs (only if a licensed professional whose scope of practice includes vaccination)**
- 5. Designated emergency medical services (EMS) providers who hold an advanced life support certificate**

III. Other Individuals Who May Vaccinate

On-site oversight from health care providers whose scope of practice includes vaccine administration is required for non-traditional vaccinators. Additional details and requirements can be found below:

- 1. Pharmacy Interns and Pharmacy Technicians:** [Department of Health and Human Services declaration](#) (HHS) allows pharmacists to order and administer childhood

vaccinations to children ages 3-18 years of age and COVID-19 vaccinations to children and adults. In addition, pharmacy interns and pharmacy technicians may administer childhood vaccines to children ages 3-18 and **COVID-19 vaccines to children and adults while under the supervision of a pharmacist as long as they meet the requirements in the declaration of the HHS Secretary.** Requirements for this provision have been defined by the [HHS](#) document. Per [§ 54.1-3320](#), the supervision of pharmacy interns and pharmacy technicians is reserved for pharmacists only. In addition, a pharmacy intern may engage in the acts to be performed by a pharmacist as set forth in subsection A of the Drug Control Act ([§ 54.1-3400](#) et seq.) for the purpose of obtaining practical experience required for licensure as a pharmacist, if the supervising pharmacist is directly monitoring these activities.

2. **EMS providers:** May provide vaccines when they meet the current requirements. In order for EMS providers to support VDH vaccination clinics, according to [§ 54.1-3408](#), they must:
 - a. Hold a valid, unrestricted Advanced Life Support certificate issued by the Virginia Commissioner of Health
 - b. Be affiliated with the Virginia EMS agency developing the vaccination program
 - c. Be individually approved by their agency Operational Medical Director (OMD) as a vaccinator
 - d. Must follow protocols approved by their OMD for vaccine administration
the Virginia EMS Agency, where the EMS provider is affiliated, shall provide confirmation to VDH that the provider meets the requirements above. Virginia EMS providers supporting VDH vaccination clinics must complete the VDH procedures for Evaluating Immunization Knowledge and Skills for Vaccinators listed below. Virginia EMS Agencies are encouraged to use VDH procedures for Evaluating Immunization Knowledge and Skills for Vaccinators for their vaccination program and closed POD vaccination efforts.
3. **MRC volunteers that are EMS providers:** Can ONLY provide vaccinations under the direction of their EMS Agency and OMD as outlined above. MRC coordinators will not be responsible for managing EMS providers as MRC volunteers.
4. **Nursing Students:** Per [§18VAC90-27-110](#), “In accordance with [§54.1-3001](#) of the Code of Virginia, a nursing student, while enrolled in an approved nursing program, may perform tasks that would constitute the practice of nursing.” **Schools of Nursing must have a current school MOA with VDH, and students must be supervised by their clinical instructor or preceptor** and in accordance with all Board of Nursing regulations.
5. **VA Students of Health Professions:** Students of those professions listed in Table 1 (students of medicine, nursing, dental medicine, midwifery, optometry, paramedic, pharmacy, physician assistant studies, podiatry, respiratory therapy, veterinary medicine, and emergency medical technician students {advanced or intermediate EMTs}) who are in good academic standing may vaccinate through VDH, LHD, or hospital community

clinic IF their school certifies that students have been properly trained in vaccination administration in compliance with the PREP act. **Schools must have a current school MOA with VDH, and students must be supervised by their clinical instructor or preceptor.**

IV. Individuals Authorized for Immediate Use Mixing, Diluting, or Reconstituting

It is anticipated that at least one of the vaccines for COVID-19 will require immediate diluting prior to use. Per [§18VAC85-20-400](#), **MD or DO may have a physician assistant or registered nurse (RN) mix vaccines without a second check by the physician provided all of the provisions set forth in the administrative code are followed.**

Pharmacists can mix, dilute or reconstitute medications including vaccines and directly supervise pharmacy interns and pharmacy technicians in the mixing, diluting or reconstituting of medications and vaccines under [§54.1-3320\(A\) \(7\)](#)

V. Required Training to Administer COVID-19 Vaccines under the Auspices of the Virginia Department of Health

Training Assumptions & Key Considerations

1. **All vaccinators will function under the guidance of a public health district director or their deputy, or public health nurse, or registered nurse in charge of COVID-19 vaccination efforts.** In addition, health districts may hire an immunization subject matter expert registered nurse, MD, DO or NP either acting under their appropriate NP qualifications or as a RN, or a Pharmacist to lead their COVID-19 vaccination efforts.
2. **All vaccinators must complete these following core training requirements** prior to participating in the vaccination event:
 - a. Moderna (TRAIN ID: 1095215) **and** Pfizer-BioNTech (TRAIN ID: 1095345) **and** Johnson & Johnson (Train ID: 1096541) Covid-19 Vaccine specific training module(s)
 - b. How to use an EPI pen (TRAIN ID: 1095208)
 - c. Needlestick Prevention (TRAIN ID: 1101015).
 - d. Complete skills checklist(s) for vaccine(s) they are administering (Refer to Appendices A-D)

Note: All training must be entered into TRAIN. Refer to the table below for direct links to these courses in TRAIN.

3. **Districts are required to maintain proof of competency on each vaccinator** in their personnel files. This includes copies of all documents verifying courses have been completed outside of TRAIN and satisfactory completion of VDH procedures for Evaluating Immunization Knowledge and Skills for Vaccinators (Skills Assessment Checklist).
4. **The Nurse Manager, District IAP, or their designee will evaluate all vaccinators** using the Skills Assessment Checklist (included as Appendix A in this document). This assessment is also an opportunity for vaccinators to ask questions, get clarification on technique, and resolve issues. The skills checklist can be completed at the vaccination site/POD. As a reminder, this function can be delegated to a competent MRC volunteer.
5. **This document will be regularly updated as additional guidance is released by the FDA and the CDC.** It is recommended that all vaccinators continue to check for regular updates to any training requirements. Vaccinators should also join the CDC Clinician Outreach and Communication Activity (COCA) Calls to continue to receive latest guidance: <https://emergency.cdc.gov/coca/calls/index.asp>

Training Requirements by Role

Traditional Vaccinators: Any provider who is authorized to administer vaccination and who has performed vaccinations in the last one (1) year. Includes those that have completed MRC training for other vaccination efforts. Volunteers are only required to take training for the vaccine they are delivering. For example, if volunteers will only be administering the COVID-19 vaccine, they do not need to complete training for administering other vaccines such as influenza, Tdap, etc. This group includes individuals currently working in health care who provide any vaccines in their health care setting (such as influenza vaccine). This group also includes individuals who are pharmacists, nurses, MDs, DOs, PAs, NPs (function as RNs), EMT-I and EMT-P who are currently authorized to vaccinate and LPNs in current practice or who have retired or left their practice setting within the last year that can complete the basic courses and demonstrate safe injection practices.

Non-Traditional Vaccinators: Any provider who is authorized to vaccinate but who does NOT have experience with administering vaccinations in the last one (1) year or have **retired/left active practice more than 1 year ago***. As the pace of vaccine production increases, additional vaccinators will be needed. Many of these vaccinators may have little or no experience in providing vaccines and are considered non-traditional vaccinators.

*If a provider previously completed training when there was a two-year requirement, the provider has met the required training to be a COVID-19 Vaccinator and does not need to take any additional training. As of March 8, 2021, any provider who has not administered a vaccine in the past one (1) year is classified as a Non-Traditional Vaccinator, and must complete all courses assigned to Non-Traditional Vaccinators.

Community Vaccinators: There is a separate training plan for those only interested in volunteering to vaccinate at COVID-19 Vaccination Clinics.

Storage & Handling Staff: Medical or non-medical staff who will be storing, handing, or managing logistics for the COVID-19 vaccines.

Other Personnel: Those in additional roles as defined by the pandemic environment such as (front desk staff, support staff, patient coordinators, POD members etc.) may be required to take certain trainings.

Table 2: Required Trainings

Topic/Course Name	Train ID (approx. duration)	Training required for the following roles:			
		Traditional Vaccinators (providers with routine vaccination experience- see definition above)	Non-traditional Vaccinators (see definition above)	Storage & Handling Staff	Other Personnel
Pfizer BioNTech Vaccine Preparation and Administration	1095215 (~25 min)	X	X		
Moderna Vaccine Preparation and Administration	1095345 (~25 min)	X	X		
J&J Vaccine Preparation and Administration	1096541 (~25 min)	X	X		
How to Use an Epi Pen ¹	1095208 (~10 min)	X	X		
Needlestick Prevention	1101015 (~15 min)	X	X		
Completion of the Skills Assessment checklist	1096532 (~20 min, see Appendix A)	X	X		
How to Give an IM Injection	1096822 (~15 min)		X		
Bloodborne Pathogens ²	1028520 (~20 min)		X		
Airborne Pathogens ²	1087669 (~20 min)		X		
Vaccinating in a pandemic environment	1095195 (~15 min)		X		

Pfizer Vaccine storage and handling	1095212 (~15 min)			X	
Returning the Pfizer thermal shipper	1095218 (~15 min)			X	
Administering Moderna Vaccine	1095345 (~15 min)			X	
Preparing and Administering J&J Vaccine	1096541 (~15 min)			X	
Working with Dry Ice	1093708 (~10 min)			X	
Confidentiality Training	1032033 (~20 min)			X	
POD Essentials	1094136 (~25 min)			X	
<i>CPR certification needs to be current within past 2 years³</i>	Can use one of several options available online such as AHA here . EMS providers must have current certification. Each EMS agency has their own policy for verifying CPR skills and the EMS may not have a current CPR card. Districts should accept the training certification by their partner EMS agency.	X	X		X
Vaccine Adverse Event Reporting System (VAERS)	VAERS Report Event				
V-safe	Quick Reference Guide				X

¹In addition to watching the Epi Pen video, all providers must complete training on responding to post vaccination emergencies such as syncope and anaphylaxis and the importance of reporting all adverse reactions to the medical POD lead for entry into VAERS. **NOTE:** The video VDH Immunization Updates for the EMS Community discusses responding to syncope.

²Vaccinators who have completed a medical bloodborne pathogen training within the last year may provide proof of official documentation through their employee health record, TRAIN transcript or official training transcript from their agency. For providers who are employed by health care systems, completion of similar courses may also be required annually by their employers and hence, such providers may be exempt from completing these again.

³Per 18VAC90-21-50. Requirements for protocols for administration of adult immunizations, the language for qualification of provider's states:

10. Qualification of immunization providers.
 - a. Virginia licensure as a registered nurse, licensed practical nurse, or pharmacist.
 - b. Supervision of a licensed practical nurse provider.
 - c. Current cardiopulmonary resuscitation training. (*Note: The agency definition of current training is "Professional CPR Certification". CPR certification is required every 2 years.*)

Storage and handling resources and EUA Fact Sheets for US COVID-19 vaccines

[Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers](#)

[Moderna COVID-19 Vaccine EUA Fact Sheet for Health Care Providers](#)

[Pfizer COVID-19 Vaccine EUA Fact Sheet for Health Care Providers 12y and older, PURPLE cap \(must dilute\)](#)

[Pfizer-BioNTech COVID-19 Vaccine Fact Sheet for Healthcare Providers, 12 and older, GRAY cap \(do not dilute\)](#)

[Pfizer COVID-19 Vaccine EUA Fact Sheet for Health Care Providers 5y to under 12y, ORANGE cap \(must dilute\)](#)

[CDC Vaccine Storage and Handling Resources](#) (general)

[CDC US COVID-19 Vaccine Product Information](#) (brand specific storage)

[VDH COVID-19 Vaccine Storage & Handling Compliance Resources](#)

VI. Pediatric Vaccinations

VDH School-Age Population Vaccination Playbook

VDH has published the "*Vaccination of the School-Age Population in a School Setting and in the Community: Playbook to Support Vaccination Events*," which can be accessed [here](#).

The playbook covers pre-planning steps, necessary communications, mapped out day-of operations, and important legal considerations. Templates for consent forms and communications, in addition to additional tools and helpful links, can also be found in the playbook. Please note that this playbook is a work in progress and will be updated in accordance with guidance from the CDC and feedback from clinic planners.

Pfizer-BioNTech COVID-19 Vaccine Fact Sheet

The FDA's vaccine information fact sheet for recipients and caregivers about the Pfizer-BioNTech COVID-19 vaccine to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals **5 through 11 years of age** is available [here](#).

FDA Vaccine Information Fact Sheet

The FDA vaccine information fact sheet for recipients and caregivers about Comirnaty (COVID-19 vaccine, mRNA) and the Pfizer-BioNTech COVID-19 vaccine to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals **12 years of age and older** is [here](#).

CDC IM Injections for Children Job Aid

The CDC *IM Injections for Children Job Aid* is available [here](#).

CDC Approved Child Vaccination Holds

CDC approved child vaccination holds are shown [here](#).

Appendix A: Skills Assessment Checklist for Covid-19 Vaccine Administration

Vaccinator's Name and Professional Credentials: _____ **Date of Assessment:** _____

Evaluator's Name and Professional Credentials: _____

Competency	Clinical skills, techniques, and procedures	Needs Improve - ment	Meets or Exceeds Expecta- tions	Req'd Plan of Action
A Patient Education	1. Welcome patient and verify identity (name) and date of birth.			
	2. Ensure the Rights of Medication Administration. Make sure you have the: <ul style="list-style-type: none"> a. Right patient b. Right vaccine with right diluent c. Right dosage d. Right route, needle length e. Right site f. Right documentation 			
	3. Explain the reason for the COVID-19 vaccination and the location of injection. Explain any follow-up shots and schedule as needed.			
	4. EMR/VASE Plus will capture precautions or contraindications. Review for appropriate vaccination or deferral.			
	5. Provide the relevant EUA COVID-19 vaccine fact sheet. This may have been provided electronically during the registration process. It is important to provide the fact sheet BEFORE administering the vaccine. Verify client/parent/caregiver receives fact sheet, ensure client/parent/caregiver has time to read information and ask questions, and provide an opportunity to discuss side effects.			
	6. Review comfort measures and aftercare instructions with patient. Answer questions and accommodate for special needs of patient. Provide information to enroll in the v-safe and VaxText programs.			
B Safety Protocols	1. Identify the location of medical protocols (e.g., immunization protocol, emergency protocol, reference material).			
	2. Identify the location of epinephrine, its administration technique, and clinical situations where its use would be indicated.			
	3. Maintain up-to-date CPR certification			
	4. Understand the need to report any needle stick injury and to maintain a sharps injury log.			

	5. Demonstrate knowledge of proper vaccine handling, e.g., maintains vaccine at recommended temperatures before and prior to use, demonstrates knowledge of how to use multi-dose vials etc.			
	6. Identify AED location.			
C Vaccine Preparation	1. Perform proper hand hygiene prior to preparing vaccine.			
	2. When removing vaccine from freezer or fridge, look to ensure storage unit temperature is in proper range.			
	3. Remove the required number of vials from storage and thaw each vial before use.			
	4. When puncturing the vial, check vial expiration date of vial and record the date and time the vial was punctured. Double check vial label and contents prior to drawing-up.			
	5. Prepare to draw vaccine in a designated clean area not adjacent to where potentially contaminated items are placed.			
	6. Follow manufacturer guidance to dilute or mix vaccine, if required (Refer to appropriate checklist for vaccine-specific protocol: Appendices B-D).			
D Administering Vaccine	1. Perform proper hand hygiene.			
	2. Utilize appropriate PPE (surgical/ procedure mask, face shield or goggles). Gloves are optional. If gloves are worn, they must be changed between each patient and hand hygiene performed.			
	3. Properly position patient. (For appropriate holds for children, please see CDC link here.)			
	4. Identify injection site (deltoid ONLY).			
	5. Locate anatomic landmark specific for IM.			
	6. Prep site with alcohol wipe, using a circular motion from the center to a 2" to 3" circle. Allow alcohol to dry.			
	7. Draw up vaccines in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed.			
	8. Select the correct needle size for IM based on patient age and/or weight, site, and recommended injection technique (23-25 Gauge Needle. Lengths may vary by body size, 5/8, 1", 1 1/2").			
	9. Maintain aseptic technique throughout, including cleaning the rubber septum (stopper) of the vial with alcohol prior to piercing it.			

	<p>10. Using aseptic technique, withdraw <u>appropriate dose</u> of vaccine into a sterile dosing syringe with a needle appropriate for intramuscular injection.</p> <p><i>Initial Vaccinations:</i></p> <ul style="list-style-type: none"> a. Moderna: 0.5mL. NO dilution is required. <u>Do not shake.</u> 18y and older. b. Pfizer-BioNTech: <ul style="list-style-type: none"> i. 12y and over: 0.3 mL of the diluted PURPLE cap Pfizer-BioNTech COVID-19 vaccine solution OR 0.3 mL of the UNDILUTED GRAY cap Pfizer-BioNTech COVID-19 vaccine solution. ii. Children 5y to under 12y: 0.2 mL of the diluted ORANGE cap Pfizer-BioNTech COVID-19 vaccine solution. NOTE: Children who will turn 12 between their first and second dose may receive either Pfizer vaccine formulation (ORANGE OR PURPLE cap). See EUA Fact Sheets for Vaccination Providers, here, for details. c. Janssen (J&J): 0.5mL. NO reconstitution or dilution is required. This vaccine is a single dose. 18y and older. <p><i>Second Vaccination in Series:</i></p> <ul style="list-style-type: none"> a. Moderna: 0.5mL 28 days after initial vaccination. No dilution is required. <u>Do not shake.</u> b. Pfizer-BioNTech: <ul style="list-style-type: none"> i. 12y and over: 0.3 mL of the diluted PURPLE cap Pfizer-BioNTech COVID-19 vaccine solution OR 0.3 mL of the UNDILUTED GRAY cap Pfizer-BioNTech COVID-19 vaccine solution at least 21 days after initial vaccination. ii. Children 5y to under 12y: 0.2 mL of the diluted ORANGE cap Pfizer-BioNTech COVID-19 vaccine solution. NOTE: Children who will turn 12 between their first and second dose may receive either Pfizer vaccine formulation (orange or purple top). See EUA Fact Sheets for Vaccination Providers, here, for details. c. Janssen (J&J): not applicable; single dose vaccine. <p><i>Additional Primary Dose Vaccinations for Immunocompromised people:</i></p> <p>Immunocompromised people ages 5 years and older should receive a COVID-19 vaccine primary series as soon as possible. Moderately to severely immunocompromised people ages 18y and older who</p>		
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	<p>received Pfizer or Moderna vaccine as primary series AND an additional primary dose are also eligible to receive a booster shot.</p> <p>a. Moderna: Moderately to severely immunocompromised people ages 18y and older: 0.5 mL at least 28 days after receipt of the 2nd primary series dose.</p> <p>Moderately to severely immunocompromised people ages 18y and older who received Moderna vaccine as primary series AND an additional primary dose should get a booster shot of any of the COVID-19 vaccines authorized in the United States.</p> <p>b. Pfizer-BioNTech: Moderately to severely immunocompromised people 5y and over: 0.3 mL of the diluted PURPLE cap Pfizer-BioNTech COVID-19 vaccine solution OR 0.3 mL of the UNDILUTED GRAY cap Pfizer-BioNTech COVID-19 vaccine solution at least 28 days after the initial 2-dose primary series.</p> <p>Moderately to severely immunocompromised people ages 18y and older who received Pfizer vaccine as primary series AND an additional primary dose should get a booster shot of any of the COVID-19 vaccines authorized in the United States.</p> <p>c. Janssen (J&J): Moderately to severely immunocompromised people 18y and older who received Janssen (J&J) COVID-19 vaccine <u>should NOT receive an additional primary dose.</u> However, they should get a booster shot of any of the COVID-19 vaccines authorized in the United States.</p> <p><i>Booster Vaccinations:</i> Everyone ages 18 and older should get a booster shot. Recipients may choose to receive ANY of the available COVID-19 vaccines as their booster at the appropriate time according to their initial vaccination(s) brand: 2 months for J&J; 5 months for Pfizer and Moderna.</p> <p>Boosters for adolescents 12-17y: Only the Pfizer-BioNTech COVID-19 vaccine is currently authorized and recommended.</p> <p>a. Moderna: 0.25 mL at least 5 months after completion of the Moderna vaccine primary series. NO dilution is required. <u>Do not</u> shake.</p>			
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	<p>b. Pfizer-BioNTech: 0.3 mL of the diluted PURPLE cap Pfizer-BioNTech COVID-19 vaccine solution OR 0.3 mL of the UNDILUTED GRAY cap Pfizer-BioNTech COVID-19 vaccine solution at least 5 months after completion of the Pfizer-BioNTech vaccine primary series.</p> <p>c. Janssen (J&J): 0.5mL at least 2 months (8 weeks) after primary dose. NO reconstitution or dilution is required.</p>			
	11. Visually inspect each dose in the dosing syringe prior to administration. Verify the final dosing volume is correct. Do not administer if the vaccine is discolored or contains particulate matter. Administer vaccine immediately once dosing syringe passes inspection.			
	12. Control limb with non-dominant hand: hold needle an inch from skin and insert quickly at appropriate angle (90 degrees for IM).			
	13. Inject vaccine using steady pressure. Do not aspirate. Withdraw needle at angle of insertion (90 degrees for IM). Use proper technique to prevent needle-stick injury, such as using the same hand to operate the safety guard on needle after injection.			
	14. Apply gentle pressure to the injection site for several seconds (use gauze pad or Band-Aid).			
	15. Dispose of needle and syringe in sharps container.			
	16. Record the date and time of first and subsequent uses of the vaccine on the vaccine vial label.			
	17. Properly dispose of vaccine vial once all doses have been exhausted. Report all wasted doses using the Vaccine Wastage Reporting Tool. This is required per the CDC agreement. https://redcap.vdh.virginia.gov/redcap/surveys/?s=YC743RTCMN			
	18. Only if the patient indicated a previous severe allergic reaction to a vaccine or injectable, or history of anaphylaxis, patient should be observed for 30 minutes. All other patients should be observed for 15 minutes. Be cognizant of the potential for vasovagal reactions.			
	19. Report any observed adverse events immediately to supervisor.			
	<p>20. Before the recipient leaves, ensure you have scheduled their second or additional primary dose as needed.</p> <p>Second Vaccination in Series:</p> <p>a. Moderna: 28 days after initial vaccination.</p> <p>b. Pfizer-BioNTech: 5y and older: at least 21 days after initial vaccination.</p> <p>c. Janssen (J&J): not applicable; single dose vaccine.</p>			

	<i>Additional Primary Dose Vaccinations for Immunocompromised people:</i> a. Moderna: Moderately to severely immunocompromised people 18y and older: at least 28 days after receipt of the 2nd primary series dose. b. Pfizer-BioNTech: Moderately to severely immunocompromised people 12y and older: at least 28 days after the initial 2-dose primary series. c. Janssen (J&J): Moderately to severely immunocompromised people 18y and older who received Janssen (J&J) COVID-19 vaccine SHOULD NOT RECEIVE AN ADDITIONAL PRIMARY DOSE. However, they should get a booster shot.			
	21. Provide the patient a filled out dose card including their second dose information. Encourage self-enrollment in VaxText.			
E Document- ation	Fully document vaccine in patient chart: date, lot number, expiration, manufacturer, injection site, vaccinator, EUA vaccine fact sheet date. This should be accomplished in EMR and/or VASE Plus.			

Plan of Action in Case of Remediation

Circle desired next steps and write in the deadline for completion, and date for the follow-up review.

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|--|--|
| 1. Watch video on immunization techniques and review CDC's Vaccine Administration eLearn, available at:
https://www.cdc.gov/vaccines/hcp/admin/resource-library.html | 8. Read Vaccine Information Statements. |
| 2. Review site/clinic protocols. | 9. Be mentored by someone who has demonstrated appropriate immunization skills. |
| 3. Review manuals, textbooks, wall charts, or other guides. | 10. Role play (with other staff) interactions with parents and patients, including age appropriate comfort measures. |
| 4. Review package inserts. | 11. Attend a skills training or other appropriate courses/training. |
| 5. Review vaccine storage and handling guidelines or videos. | 12. Attend healthcare customer satisfaction or cultural competency training. |
| 6. Observe other staff with patients. | 13. Renew CPR certification. |
| 7. Practice injections. | 14. Other _____ |

File the Skills Assessment Checklist in the employee's personnel folder.

Plan of Action Deadline (if applicable): _____

Date of Next Review (if applicable): _____

Employee/Volunteer Signature & Date: _____

Supervisor Signature & Date: _____

Appendix B: Guidance and Skills Assessment Checklist for Individuals Involved in Storage and Handling of the Moderna Covid-19 Vaccine

NOTE: This training is in addition to guidance provided on routine storage and handling on the CDC website.

Specific training for [Storage and Handling of the Moderna COVID-19 Vaccine](#) is located on the CDC web site. ALL guidance from CDC MUST be followed when storing and handling Moderna COVID-19 vaccine. Links to useful CDC resources are linked below:

1. [Storage and Handling Summary](#)
2. [Moderna BUD Guidance and Labels](#)
3. [Storage and Handling Labels](#)
4. [Refrigerator Storage Temperature Log \(Celsius\)](#)
5. [Refrigerator Storage Temperature Log \(Fahrenheit\)](#)
6. [Freezer Storage Temperature Log \(Celsius\)](#)
7. [Freezer Storage Temperature Log \(Fahrenheit\)](#)
8. [Vaccine Storage Troubleshooting Record for temperature excursions](#)
9. [U.S Pharmacopeia \(USP\) COVID-19 Vaccine Storage and Handling Toolkit](#) (includes guidance for labeling individual syringes that are being transported off site)

Competency	Clinical skills, techniques, and procedures	Needs Improvement	Meets or Exceeds Expectations	Req'd Plan of Action
<div style="background-color: #cccccc; border-radius: 50%; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center; margin: 0 auto;">A</div> Vaccine Preparation for Moderna COVID-19 vaccine	1. Perform proper hand hygiene prior to preparing vaccine.			
	2. When removing the vaccine from freezer, look to ensure storage unit temperature is in proper range.			
	3. Remember that, Moderna COVID-19 vaccine multi-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.			
	4. Remove the required number of vials from storage and thaw each vial before use. Thaw in refrigerated conditions between 2 to 8 °C (36 to 46 °F) for 2 hours and 30 minutes for the maximum 11-dose vial, or 3 hours for the maximum 15-dose vial.			
	5. After thawing, let the vial stand at room temperature for 15 minutes before administering. Alternatively, thaw at room temperature between 15 to 25°C (59 to 77°F) for 1 hour for the maximum 11-dose vial, or 1 hour and 30 minutes for the maximum 15-dose vial. After thawing, do not refreeze.			

	6. Check the expiration date of vial. Double check vial label and contents prior to drawing-up.			
	7. Prepare to draw vaccine in a designated clean area not adjacent to where potentially contaminated items are placed.			
	8. Swirl vial gently after thawing and between each withdrawal. <u>Do not dilute. Do not shake. If vials are shaken instead of swirled do not use and contact the manufacturer.</u>			
	9. Moderna COVID-19 vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.			
	10. Report all wasted doses using the Vaccine Wastage Reporting Tool. This is required per the CDC agreement. https://redcap.vdh.virginia.gov/redcap/surveys/?s=YC743RTCMN			
B Storage and Handling for Moderna COVID-19 vaccine	1. Unpunctured vials may be kept between 8°C and 25°C (46°F and 77°F) for up to 24 hours. Unpunctured vials may be kept refrigerated at 2° to 8°C (36° to 46°F) for 30 days.			
	2. Punctured vials , stored between 2-25°C (36-77°F), MUST be discarded if vaccine is not used within 12 hours of the time the vial is first punctured. Do not puncture the vial stopper more than 20 times. After a vial is punctured 20 times it is to be discarded even if the 12 hour time limit has not been met.			

Plan of Action

Circle desired next steps and write in the deadline for completion, and date for the follow-up review.

- | | |
|--|--|
| 1. Review site/clinic protocols. | 6. Read Vaccine Information Statements. |
| 2. Review manuals, textbooks, wall charts, or other guides. | 7. Be mentored by someone who has demonstrated appropriate skills. |
| 3. Review package inserts. | 8. Attend a skills training or other appropriate courses/training. |
| 4. Review vaccine storage and handling guidelines or videos. | 9. Other _____ |
| 5. Observe other staff with patients. | |

File the Skills Assessment Checklist in the employee's personnel folder.

Plan of Action Deadline (if applicable): _____

Date of Next Review (if applicable): _____

Employee/Volunteer Signature & Date: _____

Supervisor Signature & Date: _____

Appendix C: Guidance and Skills Assessment Checklist for Individuals Involved in Storage and Handling of the Pfizer-BioNTech Covid-19 Vaccine

NOTE: This training is in addition to guidance provided on routine storage and handling on the CDC website.

Update: [Pfizer-BioNTech vaccine may now be stored in a conventional freezer for up to 2 weeks or in the regular refrigerator at 2°C to 8°C \(35°F to 46°F\) for up to 31 days](#). For freezer storage, it must be set to -25°C and -15°C. If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.

Specific training for [Storage and Handling of Pfizer-BioNTech COVID-19 Vaccine](#) is located on the CDC web site as well as on the [Pfizer-BioNTech manufacturer website](#). ALL guidance from CDC MUST be followed when storing and handling Pfizer BioNTech COVID-19 vaccine. Links to useful resources are linked below (note that some resources may not yet include the latest update on storing vials at conventional freezer temperatures):

1. [Storage and Handling Summary](#)
2. [Pfizer BUD Guidance and Labels](#)
3. [Freezer Storage Guidelines \(page 52, #19\)](#)
4. [Delivery Checklist](#)
5. [Storage and Handling Labels](#)
6. [Vaccine Expiration Date Tracking Tool](#)
7. [Refrigerator Storage Temperature Log \(Celsius\)](#)
8. [Refrigerator Storage Temperature Log \(Fahrenheit\)](#)
9. [Ultra-Cold Vaccine Storage Temperature Log \(Fahrenheit\)](#)
10. [Ultra-Cold Vaccine Storage Temperature Log \(Celsius\)](#)
11. [Vaccine Storage Troubleshooting Record for temperature excursions](#)
12. [Dry Ice Safety](#)
13. [U.S Pharmacopeia \(USP\) COVID-19 Vaccine Storage and Handling Toolkit](#) (includes guidance for labeling individual syringes that are being transported off site)

Competency	Clinical skills, techniques, and procedures	Needs Improvement	Meets or Exceeds Expectations	Req'd Plan of Action
A Unpacking and moving vials to ULT Freezer or Using the Thermal Shipper	1. Upon receipt, disable GPS tracker by pressing the stop button on device. Inspect the package for damage and quantity. Report shipment issues immediately to supervisor.			
	2. Don dry ice gloves. Remove ice pod from shipper. Take vials out of payload sleeve to ULT freezer, this must be done in less than 5 minutes to prevent thawing.			
	3. When removing tray from thermal shipper, minimize the time the shipper is open to no more than 2 times per day for up to 3 minutes each time. Use packaging tape to reseal the outer carton after each entry.			
	4. IF ULT FREEZER IS NOT AVAILABLE: Don dry ice gloves. Dispense ice pellets into shipper per icing instructions provided.			
	5. Close the box to ensure the box is sealed appropriately.			
	6. Add additional dry ice every five days accordingly.			
B Storage and Handling outside ULT	1. IF STORED IN FREEZER: Before mixing, the vaccine may be stored in the freezer between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks. This beyond-use date replaces the manufacturer's expiration date. The total time vials are stored at these temperatures should be tracked and should not exceed 2 weeks. If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.			
	2. IF STORED IN FRIDGE: Refrigerator must be set to 2°C – 8°C (36°F - 46°F) for up to 31 days. Do NOT refreeze thawed vaccine. After 31 days, discard vials following manufacturer and jurisdiction guidance on proper disposal.			
	3. IF STORED AT ROOM TEMPERATURE: Unpunctured vials cannot be kept at room temperature, up to 25°C (77°F), for more than 2 hours (including thaw time). The amount of time needed to thaw vaccine varies based on temperature and number of vials. Once mixed, vaccine can be left at room temperature (2°C to 25°C [35°F to 77°F]) for up to 6 hours. Discard any unused mixed vaccine after 6 hours. Minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.			
	4. Vaccine vials should not be shaken. Right before use, the vaccinator should invert and evert the vials gently to mix. Take care not to shake any vials.			

	<p>5. Report all wasted doses using the Vaccine Wastage Reporting Tool. This is required per the CDC agreement.</p> <p>https://redcap.vdh.virginia.gov/redcap/surveys/?s=YC743RTCMN</p>			
<p>C</p> <p>Vaccine Preparation & Dilution</p>	<p>1. Thaw vaccine in the refrigerator or at room temperature. Amount of time needed to thaw vaccine varies based on temperature and number of vials. In refrigerator: Between 2°C and 8°C (36°F and 46°F). At room temperature (for immediate use): Up to 25°C (77°F).</p> <p>Choose the correct vaccine formulation based on the age of the recipient and equipment, including the correct needle size.</p> <p>a. There are 2 available vaccines for persons 12Y AND OLDER.</p> <p>i. PURPLE cap and may have a purple border on the label. This formulation must be diluted.</p> <p>ii. GRAY cap and label with gray border. Do NOT dilute this formulation.</p> <p>b. The vial for CHILDREN 5Y TO UNDER 12Y has an ORANGE cap and orange border on the label.</p>			
	<p>2. Vials MUST be discarded if vaccine is not used within 6 hours of the time the vial is punctured and stored between 2-25° C (35-77° F) during this time. Unpunctured vials cannot be kept at room temperature (up to 25°C /77°F), for more than 2 hours (including thaw time). Unpunctured vials at room temperature must be diluted within 2 hours.</p>			
	<p><u>Pfizer Vaccine must be diluted prior to use.</u></p>			
	<p>3. Gather Supplies Required to Prepare Vaccine:</p> <ul style="list-style-type: none"> 1 Vial appropriate Pfizer-BioNTech COVID-19 Vaccine <ul style="list-style-type: none"> One PURPLE cap vial = Six (6) 30 mcg doses in 0.3 mL injections. 12y and older One GRAY cap vial = Six (6) 30 mcg doses in 0.3 mL injections. 12y and older. Do not dilute. One ORANGE cap vial = up to ten (10) 20 mcg doses in 0.2 mL injections. Children 5y to under 12y 1 Vial 0.9% Sodium Chloride Injection (at least 2 mL) 1 diluent syringe/needle (3 mL syringe/21 G needle rec.) Dosing syringes/needles (1 ml syringe/IM injection needle, with age appropriate needle) Other ancillary materials such as swabs, gloves, PPE Sharps container 			

4.	Invert vial gently ten times to mix. DO NOT shake. <i>The amount of time needed to thaw Pfizer-BioNTech COVID-19 Vaccine varies based on temperature and number of vials.</i>			
5.	Cleanse the stopper with single use antiseptic swab.			
6.	<ul style="list-style-type: none"> ● PURPLE cap: Insert 1.8 mL of air into the 0.9% Sodium Chloride Injection, USP. 12y and older ● ORANGE cap: Insert 1.3 mL of air into the 0.9% Sodium Chloride Injection, USP. Children 5y to under 12y ● GRAY cap: do not dilute. 			
7.	<ul style="list-style-type: none"> ● PURPLE cap: With the needle still in the vial, withdraw 1.8ml of the 0.9% Sodium Chloride Injection, USP. 12y and older ● ORANGE cap: With the needle still in the vial, withdraw 1.3 mL of the 0.9% Sodium Chloride Injection, USP. Children 5y to under 12y ● GRAY cap: do not dilute. 			
8.	<p>Remove the needle from the Sodium Chloride and insert it into the thawed COVID-19 vaccine.</p> <ul style="list-style-type: none"> ● PURPLE cap: Insert 1.8 mL of 0.9% Sodium Chloride Injection, USP (Bacteriostatic saline or other diluents must <u>not</u> be used). 12y and older ● ORANGE cap: Insert 1.3 mL of 0.9% Sodium Chloride Injection, USP (Bacteriostatic saline or other diluents must <u>not</u> be used). Children 5y to under 12y ● GRAY cap: do not dilute. 			
9.	<ul style="list-style-type: none"> ● PURPLE cap: Ensure vial pressure is equalized by withdrawing 1.8 mL air into the empty diluent syringe before removing the needle from the vial. 12y and older ● ORANGE cap: Ensure vial pressure is equalized by withdrawing 1.3 mL air into the empty diluent syringe before removing the needle from the vial. Children 5y to under 12y ● GRAY cap: do not dilute. 			
10.	Remove the needle and discard the needle and syringe into the sharps container. IMPORTANT: Regardless of the volume of the diluent vial, it can only be used ONE TIME for dilution. (After 1.8 mL withdrawal, the remaining diluent MUST be discarded).			
11.	Invert gently ten times to mix. Do not shake. If unable to get a 6 th dose from the vial, report it as wastage.			

	12. The vaccine will be off-white in color. Do not use if discolored or contains particulate matter.			
	13. Note the date and time the vaccine was mixed on the vial. Keep mixed vaccine between 2°C and 25°C (36°F to 77°F), with minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Administer within 6 hours. <u>Discard any unused vaccine after 6 hours.</u> Do not return to freezer storage.			

<i>Plan of Action</i>	1. Review site/clinic protocols.	6. Read Vaccine Information Statements.
Circle desired next steps and write in the deadline for completion, and date for the follow-up review.	2. Review manuals, textbooks, wall charts, or other guides.	7. Be mentored by someone who has demonstrated appropriate skills.
	3. Review package inserts.	8. Attend a skills training or other appropriate courses/training.
	4. Review vaccine storage and handling guidelines or videos.	9. Other _____
	5. Observe other staff with patients.	

File the Skills Assessment Checklist in the employee's personnel folder.

Plan of Action Deadline (if applicable): _____

Date of Next Review (if applicable): _____

Employee/Volunteer Signature & Date: _____

Supervisor Signature & Date: _____

Appendix D: Guidance and Skills Assessment Checklist for Individuals Involved in Storage and Handling of the Janssen (J&J) Covid-19 Vaccine

NOTE: This training is in addition to guidance provided on routine storage and handling on the CDC website.

Specific training for [Storage and Handling of the J&J COVID-19 Vaccine](#) is located on the CDC web site. ALL guidance from CDC MUST be followed when storing and handling J&J COVID-19 vaccine. Links to useful resources are linked below:

1. [J&J Vaccine Storage and Handling Summary](#)
2. [Storage, Dosage, and Administration Guide, Video, and Other Resources](#)
3. [Refrigerator Storage Temperature Log \(Celsius\)](#)
4. [Refrigerator Storage Temperature Log \(Fahrenheit\)](#)
5. [J&J Vaccine Storage and Handling Labels](#)
6. [Transport Guidance Summary](#)
7. [Transport Temperature Log](#)
8. [Vaccine Storage Troubleshooting Record for temperature excursions](#)
9. [U.S Pharmacopeia \(USP\) COVID-19 Vaccine Storage and Handling Toolkit](#) (includes guidance for labeling individual syringes that are being transported off site)

Competency	Clinical skills, techniques, and procedures	Needs Improvement	Meets or Exceeds Expectations	Req'd Plan of Action
A Vaccine Preparation for Janssen J&J COVID-19 Vaccine	1. Perform proper hand hygiene prior to preparing vaccine.			
	2. If vaccine is still frozen upon receipt, thaw at 36°F to 46°F (2°C to 8°C). If needed immediately, thaw at room temperature (maximally 77°F/25°C). At room temperature, a carton of 10 vials will take ~2 hours to thaw, and an individual vial will take ~1 hour to thaw. Do not re-freeze once thawed.			
	3. Remove the required number of vials from storage and thaw each vial before use.			
	4. When removing vaccine from fridge look to ensure storage unit temperature is in proper range.			
	5. Check vial expiration date of vial. Double check vial label and contents prior to drawing-up. Record the date and time of first use on the Janssen J&J COVID-19 Vaccine vial label.			

	6. The J&J COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent sterile suspension that does not contain a preservative. Visually inspect the J&J COVID-19 Vaccine vials for particulate matter and discoloration prior to administration. If either of these conditions exist, do not administer the vaccine. Visually inspect each dose in the dosing syringe prior to administration.			
	7. Prepare to draw vaccine in a designated clean area not adjacent to where potentially contaminated items are placed.			
	8. Carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. Do not shake.			
	9. Report all wasted doses using the Vaccine Wastage Reporting Tool. This is required per the CDC agreement. https://redcap.vdh.virginia.gov/redcap/surveys/?s=YC743RTCMN			
<div style="background-color: #cccccc; border-radius: 50%; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center; margin: 0 auto;">B</div> Storage and Handling for Janssen J&J COVID-19 vaccine	1. Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 36°F to 46°F (2°C to 8°C) and protect from light. Do not store frozen.			
	2. Unpunctured vials of the vaccine may be stored between 47°F to 77°F (9°C to 25°C) for up to 12 hours.			
	3. After the first dose has been withdrawn , hold the vial between 36°F and 46°F (2°C to 8°C) for up to 6 hours or at room temperature (maximally 77°F/25°C) for up to 2 hours. Discard the vial if vaccine is not used within these times.			

Plan of Action Circle desired next steps and write in the deadline for completion, and date for the follow-up review.	1. Review site/clinic protocols.	6. Read Vaccine Information Statements.
	2. Review manuals, textbooks, wall charts, or other guides.	7. Be mentored by someone who has demonstrated appropriate skills.
	3. Review package inserts.	8. Attend a skills training or other appropriate courses/training.
	4. Review vaccine storage and handling guidelines or videos.	9. Other _____
	5. Observe other staff with patients.	

File the Skills Assessment Checklist in the employee's personnel folder.

Plan of Action Deadline (if applicable): _____

Date of Next Review (if applicable): _____

Employee/Volunteer Signature & Date: _____

Supervisor Signature & Date: _____